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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,934	04/07/2006	Satomi Miyata	MIYATA 6	5550
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Suite 1100 Washington, E	oc 20006		ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

Application No.	Applicant(s)	
10/574,934	MIYATA ET AL.	
Examiner	Art Unit	
Isis Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS.

- WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  - earned patent term adjustment. See 37 CFR 1.704(b).

Status	
1)🖂	Responsive to communication(s) filed on <u>22 February 2010</u> .
2a)	This action is <b>FINAL</b> . 2b) ☑ This action is non-final.
3)	An election was made by the applicant in response to a restriction requirement set forth during the interview on
	the restriction requirement and election have been incorporated into this action.

4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

5)🛛	Claim(s) 17,20 and 26-34 is/are pending in the application.
	5a) Of the above claim(s) is/are withdrawn from consideration.
6)	Claim(s) is/are allowed.
7)🛛	Claim(s) 17, 20, 26-34 is/are rejected.
8)	Claim(s) is/are objected to.
9)	Claim(s) are subject to restriction and/or election requirement.

#### Application Papers

- 10) The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

owledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
b) ☐ Some * c) ☐ None of:
Certified copies of the priority documents have been received.
Certified copies of the priority documents have been received in Application No
Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).
e attached detailed Office action for a list of the certified copies not received.

Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413)	
Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date	
3) Information Disclosure Statement(s) (FTO/SB/08)	5). Notice of Informal Patert Application	
Paper No(s)/Mail Date .	6) Other:	

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 02/22/2010.

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/22/2010 has been entered.

Claims 17, 20, 26-32 previously presented.

Claims 33 and 34 are currently added.

Claims 17, 20, 26-34 are pending and included in the prosecution.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17, 20, 26-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claims 17 and 31 recite "isolated saccharide derivative of L-ascorbic acid. Recourse to the specification, nowhere applicants recite isolated ingredient as claimed. Applicants refer to page 13, lines 9-18, and examples 1-3 for support. However, upon careful review to entire specification, no support was found to the isolated L-ascorbic acid derivative. Applicants stating:

"Examples 1-3 uses L-ascorbic acid 2-glucoside, "AA2G", a product made and commercialized by Hayashibara Blochemical Laboratories, Inc., Okayama, Japan. One skilled in the art would readily assume that this product is isolated L-ascorbic acid 2-glucoside, as one would expect that a commercial product marketed as a compound per se would be isolated, i.e., free of other compounds or impurities. Submitted herewith is a copy of "Business Information" describing AA2G L-ascorbic acid 2-glucoside, manufactured by Hayashibara Biochemical Laboratories. Page 2 of this printout states that the company "successfully synthesized" L-ascorbic acid 2-glucoside. Clearly, this is an isolated compound."

It is the examiner position that "successfully synthetized" does not impart by any mean the isolated compound because it is not known what else in the "AA2 $G^{TMn}$ .

Additionally, new claim 33 recites method for enhancing collagen production comprising administering composition consisting of (a) a saccharide derivative of L-ascorbic acid; (b) 10-hydroxy-20-decenoic acid; and (c) a physiologically acceptable carrier. However, nowhere applicant disclosed composition consisting of the only three claimed elements. All the examples disclosed additional ingredients.

If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983). See MPEP 2163.06.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him. See *Genetech.* 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

#### Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

 Claims 33-34 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 2003-171290 ('290) as evident by JP 10-147514 ('514) or JP 09-315928 ('928), all references are of record.

Claim 33 is directed to a method for enhancing collagen production, comprising: administering a composition to a living body, said composition consisting of (a) a saccharide derivative of L-ascorbic acid; (b) IO-hydroxy-20-decenoic acid; and (c) a physiologically acceptable carrier.

JP '290 discloses method for producing collagen production potentiator capable of continuously exhibiting action of potentiating the collagen production by using composition comprising L-ascorbic acid and royal jelly as active ingredient (abstract; paragraph 0008). The L-ascorbic acid is L-ascorbic acid 2-glucoside (AA2G) compound, (paragraph 0011). The teaching of the AA2G compound implies its presence as isolated compound. The composition comprising by weight 0.001 to 20% of each of L-ascorbic acid derivative or royal jelly (paragraph 0019), this disclosure of the reference implied that L-ascorbic acid derivative is present in at least 0.01% of the composition. JP '290 disclosed that the composition can be a cosmetic, food, quasi drug or feed (claim 10, paragraph 0019). Royal jelly undergoes solvent extraction, gel filtration and others, i.e. purified (paragraph 0013, 0019). The composition further comprises antioxidant, thickeners, sugar and sugar alcohol, gums, water, alcohol, amino acid, vitamin, mineral flavor, emulsifier, seasoning, spices, all read on physiologically acceptable carrier

(paragraphs: 0015-0020). Royal jelly inherently contains 10-hydroxy- 2-decenoic acid as evident by the disclosure of JP '514 as it discloses that 10-hydroxy- 2-decenoic acid is an active ingredient of royal jelly (Problem to be solved; paragraphs 0005, 0012), or as evident by JP '928 that discloses compounds of royal jelly origin comprising 10-hydroxy-2-decenoic acid (abstract; paragraphs 0007; claims 1 and 2).

The limitations of claims 33 and 34 are met by JP '290.

#### Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - Determining the scope and contents of the prior art.
  - Ascertaining the differences between the prior art and the claims at issue.
  - Resolving the level of ordinary skill in the pertinent art.
  - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 17, 20, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2003-171290 ('290) in view of JP 09-315928 ('928), both reference are of record

#### Applicant Claims

Applicants' claim 17 is directed to a method for enhancing collagen production, comprising

administering a composition to a living body, comprising said composition being prepared by a step of mixing (i) an isolated saccharide derivative of L-ascorbic acid, (ii) an isolated 10-hydroxy-2-decenoic acid, to enhance the collagen production by (i), and (iii) a physiologically acceptable carrier, said composition wherein the L-ascorbic acid in the saccharide derivative of L-ascorbic is present in an amount of at least 0.01% (w/w), of L-ascorbic acid of the total weight of said composition, and (ii) in an amount of at least 0.0001 part by weight to one part by weight of (i), in terms of the weight of L-ascorbic acid present in said isolated Saccharide derivative of L-ascorbic acid.

Claim 31 is directed to a composition for enhancing collagen production, said composition being prepared by mixing (i) an isolated saccharide derivative of L-ascorbic acid, (ii) an isolated 10-hydroxy-2-decenoic acid to enhance the collagen production by (i), and (iii) a physiologically acceptable carrier, wherein the L-ascorbic acid present in the saccharide in an amount of at least 0.01% (w/w) of L-ascorbic acid is present in terms of the weight of L-ascorbic acid of the total weight of said composition, and (ii) the L-ascorbic acid is present in an amount of at least 0.0001 part by weight to one part by weight of (i), in terms of the weight of L-ascorbic acid present in said isolated saccharide derivative of L-ascorbic acid

Claim 33 is directed to a method for enhancing collagen production, comprising: administering a composition to a living body, said composition consisting of (a) a saccharide derivative of L-ascorbic acid; (b) IO-hydroxy-20-decenoic acid; and (c) a physiologically acceptable carrier.

# Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

JP '290 teaches method for producing collagen production potentiator capable of continuously exhibiting action of potentiating the collagen production by using composition comprising L-ascorbic acid and royal jelly as active ingredient (abstract; paragraph 0008). The L-ascorbic acid is L-ascorbic acid 2-glucoside (AA2G) compound, (paragraph 0011). The teaching of the AA2G compound implies its presence as isolated

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compound. The composition comprising by weight 0.001 to 20% of each of L-ascorbic acid derivative or royal jelly (paragraph 0019), this disclosure of the reference implied that L-ascorbic acid derivative is present in at least 0.01% of the composition. JP '290 disclosed that the composition can be a cosmetic, food, quasi drug or feed (claim 10, paragraph 0019). Royal jelly undergoes solvent extraction, gel filtration and others, i.e. purified (paragraph 0013, 0019). The composition further comprises antioxidant, thickeners, sugar and sugar alcohol, gums, water, alcohol, amino acid, vitamin, mineral flavor, emulsifier, seasoning, spices, all read on physiologically acceptable carrier (paragraphs: 0015-0020). The reference further teach cosmetics that containing mucopolysaccharides such as hyaluronic acid have been developed as cosmetic for aging prevention in order to secure the moistness of the skin (paragraph 0006).

### Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

While JP '290 teaches the use of royal jelly to enhance the production of collagen, and suggested extraction of royal jelly, however, the reference does not explicitly teach isolated 10-hydroxy-2-decenoic acid as instantly claimed by claims 17 and 31, or 10-hydroxy-2-decenoic acid as claimed by instant claim 33.

JP '928 that discloses compounds obtained from royal jelly origin comprising 10hydroxy-2-decenoic acid by extraction. 10-hydroxy-2-decenoic acid is useful for beautifying cosmetic and has no skin irritation and excellent skin adaptability. It can be

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added to the cosmetic in an amount of 1-20 wt % (abstract; paragraphs 0007, 0014; claims 1 and 2).

### Finding of Prima Facie Obviousness Rational and Motivation (MPEP \$2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to potentiate collagen production in the skin by using composition comprising L-ascorbic acid-2-glucoside and royal jelly as taught by JP '290, and use 10-hydroxy-2-decenoic acid extracted from royal jelly taught by JP '928. One would have been motivated to do so because JP '928 teaches that 10-hydroxy-2-decenoic acid extracted from royal jelly has no skin irritation and excellent skin adaptability. One would reasonably expect safely potentiating collagen production in the skin by using composition comprising L-ascorbic acid-2-glucoside and 10-hydroxy-2-decenoic acid extracted from royal jelly without having skin irritation or incompatibility.

Regarding the claimed of L-ascorbic acid-2-glucoside and 10-hydroxy-2-decenoic acid, JP teaches each can be present in an amount ranging from amounts of 0.001 to 20%, which overlaps with the instantly claimed amounts. Therefore, the amounts and corresponding ratio overlaps with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See MPEP 2144.05 [R-5].

Regarding claims 26 and 32, JP '290 teaches that it was known to include hyaluronic acid in cosmetic composition for aging prevention in order to secure the

moistness of the skin. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to include hyaluronic acid in the composition comprising L-ascorbic acid-2-glucoside and 10-hydroxy-2-decenoic acid. One would have been motivated to do so because JP '290 teaches that hyaluronic acid is known to be included in cosmetic for aging prevention in order to secure the moistness of the skin. One would reasonably expected formulating composition comprising saccharide L-ascorbic acid-2-glucoside and 10-hydroxy-2-decenoic acid and hyaluronic acid, wherein the composition potentiates the production of collagen and prevents aging and further secures the moistness of the skin.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable
 over JP 2003-171290 ('290) in view of JP 09-315928 ('928) as applied to claims 17, 20,
 27-31, 31, and further in view JP 2000-159656 ('656), all reference are of record.

### Applicant Claims

Claims 26 and 32 further recite glycosaminoglycan selected from chondroitin, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate, keratan sulfate, hyaluronic acid, and mixtures thereof.

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## Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of JP '290 and JP '928 are previously discussed in this office action.

# Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

While JP '290 teaches cosmetics that containing mucopolysaccharides such as hyaluronic acid have been developed as cosmetic for aging prevention in order to secure the moistness of the skin, however, the reference does not explicitly teach addition of such a compound to its composition.

JP '656 teaches cosmetic composition having collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention (abstract). The composition comprises ascorbic acid derivative and hyaluronic acid (paragraphs 0010, 0017, 0018).

### Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to potentiate collagen production in the skin by using composition comprising L-ascorbic acid-2-glucoside and 10-hydroxy-2-decenoic acid

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extracted from royal jelly as taught by the combination of JP '290 and JP '928, and further add hyaluronic acid taught by JP '656 to the composition. One would have been motivated to do so because JP '290 teaches the advantage of hyaluronic acid in preventing aging and because JP '656 teaches that composition comprising hyaluronic acid and ascorbic acid derivatives provides collagen synthesis accelerating effect, excellent in stability and provides cosmetic excellent in wrinkles prevention. One would reasonably expected potentiating collagen production in the skin by using composition comprising L-ascorbic acid-2-glucoside and 10-hydroxy-2-decenoic acid extracted from royal jelly and hyaluronic acid, wherein the composition have collagen synthesis accelerating effect and excellent in wrinkles prevention, meanwhile is table and safe to the skin.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

#### Response to Arguments

 Applicant's arguments filed 02/22/2010 have been fully considered but they are not persuasive.

The basis for applicants' argument is that claims 17 and 31 have been amended to recite that the composition is prepared by mixing (i) an isolated saccharide derivative of L-ascorbic acid and (ii) an isolated 10-hydroxy-2-decenoic acid with (iii) a

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physiologically acceptable carrier. In contrast thereto, Miyata (JP '290) discloses enhancing collagen production using royal jelly as the active ingredient and not isolated 10-hydroxy-2-decenoic acid that applicants show to be superior to royal jelly.

In response to this it is argued that the present claims are directed to method for enhancing collagen production comprising administering composition comprising....., and the method of making the composition by "mixing" does not impart patentability to the claims. In any event the claimed method is conventional method does not have any steps other than mixing which is implied by the reference. JP '290 teaches using the compound AA2G which implies that the compound is isolated. In view of the new ground of rejection, JP '290 in view of JP '928, isolated 10-hydroxy-2-decenoic acid is taught by JP '928.

In response to the argument that inventors have identifying 10-hydroxy-2-decenoic in royal jelly are effective in enhancing the collagen production of a saccharide derivative of L-ascorbic acid, it is argued that this is not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). The fatty acids of royal jelly and their effect on collagen were known at the time of the invention. The discovery of a new action underlying a known process or composition does not make it patentable. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. Also, it is irrelevant that the prior art observers did not recognize the property or function of the disputed claim; if the prior art inherently possessed that

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characteristic, it anticipates. See Verdeegal Brothers, Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 633, 2 U.S.P.Q.2d 1051, 1054 (Fed. Cir. 1987).

It is argued that the present invention as whole is taught by the combined teachings of the cited prior art. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray- dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." KSR Int 1 Co. v. Teleflex Inc., 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. AG Pro, Inc., 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be

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made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXING. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima* facie obvious within the meaning of 35 U.S.C. 103 (a).

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Isis A Ghali/ Primary Examiner, Art Unit 1611